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REMARKS

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Claims 1, 4, 7, 11, 14, and 17 have been amended.

#### Drawings

The objection to the drawings as not including all of the elements as claimed in claims 3, 7, 14, and 17 is believed to be overcome by amendments to the specified claims. Specifically, claims 3 and 14 have been amended to claim a "barbed head" as described in the specification and particularly designated in the drawings by the reference numeral 24. With respect to claims 7 and 17, the reference to a tool which may engage the engaging member has been deleted and a "tool engaging element" specified. This element is clearly shown in the drawings as element 34. No "tool" is claimed therefore no illustration of a "tool" is required. Withdrawal of the objection to the drawings is requested.

## Double Patenting

Claims 1, 11 and 20 are rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1 and 14 of U.S. Patent No. 6,286,510B1. While the end result of blocking an oviduct is the goal of both devices, how this result is achieved is different. Specifically, the manner in which the device is anchored to permit

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fibroblast ingrowth is markedly different. The present invention as claimed, does not resort to "engaging the oviduct", but in fact is anchored to the uterine cavity wall. The claimed structure is completely different and does not anchor the device in the same manner nor does the patent '510 suggest this structure. Since there is no teaching or suggestion of this anchoring structure, there can be no obviousness. Withdrawal of the rejection is respectfully requested.

U.S. Patent No. 6,286,510B1 claims "an insert for insertion into the oviduct through the opening leading from the uterine cavity to the oviduct" and "an engagement element supported by the insert for securing the insert to the oviduct." Since the engagement element is carried by the insert, and the insert is for insertion into the oviduct, the engagement element is also for insertion into the oviduct. This is supported by the language for "securing to the oviduct". Claim 14 specifically claims an engagement element for engaging the oviduct. Thus, this patent specifies that an engagement element carried by the insert is for engaging the oviduct.

In the present application, claims 1, 11 and 20 specifically claim that a peripheral anchor portion extends from the base or body and engages uterine tissue. The most profound difference is that the peripheral anchor is specifically for engaging the uterine tissue while the

engagement element of patent '510 is specifically for engaging the oviduct. These are two very specific and different tissues in different areas requiring different structures to work. The specific structure required for the engaging the uterine tissue is a **peripheral** anchor. This cannot be the case in patent '510 since that device requires an engagement element carried by the insert and the insert must pass through the opening and enter the oviduct.

Claims 1, 11 and 20 are rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1, 6 and 11 of U.S. Patent No. 6,371,118B1. Withdrawal of the rejection is respectfully requested for the same reasons as described above. Specifically, the "insert" of the '118 patent does not read on "body" because the "insert" is specifically inserted into the oviduct which is not and cannot be done with the "body". "Second portion" does not read on "peripheral anchor" because it is not a peripheral anchor, and cannot accomplish any of the functions thereof. Simply matching one element with another element does not support obviousness, most particularly when those elements do not have the same structure and cannot function in the same manner.

# 35 U.S.C. §112 rejections

The rejection of claims 2-4 and 12-14 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is believed to improper. Claims 2 and 12 depend from claims 1 and 11, respectively which claim a "peripheral anchor portion". Claims 2 and 12 specifically claim that the "peripheral anchor portion" comprises a "plurality of spikes". There is nothing ambiguous or difficult to understand about this language. There is a peripheral anchor portion, and in a specific embodiment as claimed in claim 2 and 12, the peripheral anchor portion is specified as a plurality of spikes. This is adequately shown in the drawings, described in the specification and claimed.

#### 35 U.S.C. §102(b) rejections

Claims 1, 7-9, 11, 17, 18 and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Zeluff. Withdrawal of the rejection is requested for the following reasons.

with respect to claims 1 and 11, the device comprises a body with a base having a periphery. A seal is carried by the body and overlies the uterine tissue around the

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opening. Claims 1 and 11 have also been amended to specifically claim a peripheral anchor portion extending from the base for "insertion into and" engaging the uterine tissue leading to the opening. Thus, claims 1 and 11 claim (1) a peripheral anchor, and (2) the anchor for insertion into and engaging the uterine tissue.

Zeluff discloses a device that does not teach or suggest an anchor. The element (20) presented in the rejection which is construed as an anchor, is in fact not Locator pin 20 of Zeluff is a centering means an anchor. simply to allow positioning of the device. Zeluff teaches using a light adhesive on locator pin 20, but this is an adhesive, not an anchor, and is in the oviduct not outside the oviduct on the uterine wall. Additionally, Zeluff teaches the possibility of a very light coat of adhesive on the lower surface of ring 24, but again, this is an adhesive, not an anchor as claimed. Additionally, claims 1 and 11 have been amended to include the anchor being inserted into the uterine tissue. This is not taught by Since each and every element as claimed in claim 1 is not taught by Zeluff there be and 11 can no anticipation.

Claims 7-9, depend from claim 1 and are not anticipated for the same reasons. Claims 17 and 18 depend from claim 11 and are not anticipated for the same reasons.

With respect to claim 20, the method includes the device as claimed in claim 1 and further includes the step of "inserting the peripheral anchor portion into the uterine tissue surrounding and defining the opening". Again, Zeluff does not teach an anchor nor does Zeluff teach inserting an anchor into the uterine tissue. Since each and every element of claim 20 has not been taught by Zeluff, there can be no anticipation.

## 35 U.S.C. §103(a) rejections

Claims 2, 10, 12 and 19 stand rejected as being unpatentable over Zeluff. Withdrawal of the rejection is requested for the following reasons. With respect to claims 2 and 12, element 20 is a locator pin, not a spike. Simply because it is an elongated element does not make it anymore than a straw is a nail. spike superficially similar appearing, each has a different structure and function. Locator pin 20 aligns the device with the oviduct and does not pierce any tissue and must be centrally located to allow proper alignment. Furthermore, additional locator pins would not function to align the device better, and in fact would not work, as only one locator pin can be centrally positioned and inserted into Therefore there is nothing to suggest that a the oviduct. plurality of peripheral spikes be inserted into the uterine wall to anchor the device in place and such a structure

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cannot be imagined from a central locator pin serving none of those functions.

With regard to claims 10 and 19, the rejection is not understood. However, simply stated, Zeluff does not teach a biodegradable body. While the current application does teach the use of other materials, claims 10 and 19 are limiting the device to biodegradable materials. Nothing in Zeluff suggests the use of biodegradable materials and therefore, claims 10 and 19 cannot be said to be obvious in view thereof.

In view of the foregoing, it is submitted that each of the claims is in condition for allowance. Withdrawal of the rejections and allowance of the claims is respectfully requested. Should there be any questions or remaining issues, Examiner is cordially invited to telephone the undersigned attorney for a speedy resolution.

Respectfully requested,

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